

Notice of Allowability

Application No.

09/970,913

Examiner

Sean E Conley

Applicant(s)

SMITH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 29, 2003.
2. ☒ The allowed claim(s) is/are 1,2,4-17,19-27,29-34,36-49,51-59 and 61-77.
3. ☒ The drawings filed on 11 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

DETAILED ACTION

Allowable Subject Matter

1. Claims 1, 2, 4-17, 19-27, 29-34, 36-49, 51-59 and 61-77 are allowed.
2. The following is an examiner's statement of reasons for allowance: The prior art fails to teach or fairly suggest discharging a sterilant vapor through a nozzle and purging the container of the discharged sterilant with gas from the same nozzle. Also, the prior art does not specifically teach positioning the nozzle through an opening in the container and to a position in a range from just below a shoulder of the container and no closer than 15 mm from any internal surface. Regarding claims 65-77, none of the prior art teaches or fairly suggests the equations as recited in independent claims 65, 70, 75.

The closest prior art to the applicant's invention are the references to Taggart (U.S. Pat. 6,209,591 B1) and Zelina et al. (U.S. Pat. Application Publication US 2002/0159915).

Taggart discloses a method and apparatus for providing a container product filling in an aseptic processing apparatus. The invention processes containers such as bottles or jars that have a small opening compared to its height and its greatest width (e.g. the ratio of the opening diameter to the height of the container is less than 1.0). In the preferred embodiment, a bottle 12 is formed of a plastic such as polyethylene terephthalate (PET). The aseptic sterilant that is used by Taggart is selected from

hydrogen peroxide or oxonia, with hydrogen peroxide being the preferred sterilant (see column 4, lines 42-55 and figure 8).

The process delivers the empty bottles to a filler apparatus **50** after passing through a bottle infeed and sterilization apparatus **60** for aseptic sterilization. The bottles **12** in the conveying plate **94** enter an interior bottle sterilization apparatus **116**. A heated hydrogen peroxide vapor fog is introduced into the interior **118** of each bottle **12** (see figures 3 and 10). The application of the sterilant is accomplished with the use of a plurality of sterilant measuring devices **121** and a plurality of probes **123**. Each probe **123** includes an applicator spray nozzle **122**, which provides uniform sterilant application without droplet formation on the interior surface **119** of the bottle **12** (see column 8, lines 17-50). After the step of applying the hydrogen peroxide vapor to the interior **118** of the bottles **12** the sterilant is purged from the bottles. The purging process introduces a heated gas into the interior of the bottles at a temperature of 131° F and for a time period of about 24 seconds (see column 12, lines 28-67). The temperature is selected based upon the heat resistance for PET bottles and that generally is about 55° C (131° F). The PET bottles may deform when exposed to temperatures above 131° F for extended periods of time.

However, Taggart does not teach or fairly suggest discharging a sterilant vapor through a nozzle and purging the container of the discharged sterilant with gas from the same nozzle. Also, Taggart does not specifically teach the step of positioning the nozzle through an opening in the container and to a position in a range from just below a shoulder of the container and no closer than 15 mm from any internal surface.

Zelina et al. disclose vapor phase decontamination of containers. Vaporized hydrogen peroxide is discharged through nozzles (128) into the interior space (130) of the containers (120). After a brief decontamination period, for example 30 seconds to one minute, a valve (180) is opening and a pump (176) withdraws the vapor from the container through the exhaust line (174). Additionally, sterile air, may be blown into the aeration chamber (182) through air inlet line (188) to drive off any remaining vapor from the containers. The containers then move to an aseptic filling area (190) where they are filled with the product and then capped.

However, Zelina et al. also fails to teach or fairly suggest discharging a sterilant vapor through a nozzle and purging the container of the discharged sterilant with gas from the same nozzle. Furthermore, Zelina et al. do not specifically teach that the nozzle is inserted into the container and no closer than 15 mm from any internal surface.

Therefore, the prior art alone or in combination, does not teach the applicant's claimed invention as recited in the currently presented claims. Specifically, the prior art fails to teach or suggest discharging a sterilant vapor through a nozzle and purging the container of the discharged sterilant with gas from the same nozzle. Also, the prior art does not specifically teach positioning the nozzle through an opening in the container and to a position in a range from just below a shoulder of the container and no closer than 15 mm from any internal surface. Furthermore, none of the prior art teaches or suggests the equations as recited in independent claims 65, 70 and 75.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (571) 272-1273. The examiner can normally be reached on Monday-Friday 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310. The direct fax number to the (571) 273-1273.

When filing a FAX in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged

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or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

Sean E. Conley
Patent Examiner
AU 1744

SEC *AC*
January 20, 2004

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